FDA 510(k) Premarket Notification

K153463 CD HORIZON Spinal System, IPC POWEREASE System

CLEARED

Dec 30, 2015
29 days to decision

K153463 · Product code: **NKB** · Orthopedic
Source: https://www.510kdatabase.net/k153463/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Dec 1, 2015
Decision date	Dec 30, 2015
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Medtronic Sofamor Danek USA, Inc.**
Location	Memphis, TN, US
Contact	Becky Ronner
510(k) history	170 submissions · 159 cleared · 2000-2026